BONE CEMENTS FOR ORTHOPAEDICS
who we are

G-21 was set up in 2009 by expert entrepreneurs originating from the medical and pharmaceutical sector.

G-21 is situated in proximity of the main cities and infrastructures in northern Italy, approximately 40 km from Modena and Bologna, in the Italian “Medical Valley” famous all over the world for its tradition, know-how and innovative spirit in the field of Medical Devices.

The company is strategically managed by a team of young people that stand out for their integrity, expertise and professionalism and who continuously bring the energy, enthusiasm and dynamism necessary to satisfy the requirements of an ever more demanding and developing market.

G-21 has its own product portfolio (among which long-term implantable devices and Class III medical devices) of which it fully possesses the know-how as well as the design and production technology, the result of Research and Development programmes conducted in-house and in collaboration with major international research institutes and Universities.

High-quality raw materials, absolute process control, compliance with the most stringent international standards, continuous personnel training and painstaking care to details: this is the profile of G-21’s in-house production unit, which includes clean rooms certified up to Class ISO 5 for process execution in 100% sterile conditions.

mission

Develop innovative and more reliable solutions in the field of biomaterials and procedures for vertebral consolidation and articular functional rehabilitation, dedicated to improving therapeutic treatment of orthopaedic patients and designed to anticipate the future needs of Medical Professionals.

Manufacture the products complying with the most stringent quality standards and distribute them internationally in collaboration with trade partners with whom establish and maintain long-term relationships based on trust, cooperation and responsibility.

certifications

Since 2010 we have been operating according to a quality system in compliance with EN ISO 13485 “Quality Management Systems - Requirements for regulatory purposes applicable to Medical Devices”.

Our Quality Management System and the CE marking on our products (in accordance with Medical Device Directive 93/42/EEC and subsequent amendments) are certified by the Cenret (no. 0476) and Det Norske Veritas (DNV, no. 0434) Notified Bodies, who also keep strict control to ensure that the quality levels achieved are maintained over time.
The G-21 bone cements spring from analysis of the best systems available on the market, processed to minimise the incidence of factors such as ambient conditions and preparation methods, which play a decisive role in determining the mechanical properties after application, putting at risk the long-term success and reliability of a prosthetic implant.

Reproducibility of performance and chemical/physical properties without compromise are the strengths of G1™ and G3™, acrylic-based (poly-methyl-meth-acrylate, PMMA) radiopaque bone cements indicated for fixation and revision of articular prostheses of the hip, knee and shoulder, repair of bone defects and pathological fractures.

Each cement - which comes in the form of a two-component system (powder and liquid) to be mixed at the time of application in the operating theatre - is formulated so as to develop the right viscosity for the type of application and such that, once hardened, it assumes a compact structure (with very low residual porosity) which enhances the mechanical strength of the implant. The cements are available in different viscosities and with and without antibiotic.

**Working properties at 23°C according to ISO 5833™**

**G1™ - G1A™**
- **Standard Viscosity**
- **Low Viscosity**

**G3™ - G3A™**
- **Low Viscosity**

2. Data on file at G-21 S.r.l.
Acrylic-based radiopaque bone cement with a consistency and working time particularly suitable for cementation of knee prostheses. In the initial phases, it has properties that also make it suitable for cementation of hip prostheses. It can be mixed and applied by hand (bowl and spatula) or using mixing and injection devices. The version with antibiotic is indicated in revision operations and in cases where there is a risk of infections caused by organisms sensitive to gentamicin. It has been demonstrated that local application of antibiotics by means of bone cement reduces the risk of septic detachment of the prosthesis, assuring high release of active ingredient in the implant site while maintaining the concentration on systemic level low.

**CHARACTERISTICS**
1. reduced mixing time (under a minute to obtain a homogeneous product),
2. working time suited to the type of application (4-5 minutes),
3. polymerisation is completed after 10 minutes so as to reduce the risk of micro movements of the prosthesis once applied,
4. excellent mechanical properties,
5. low polymerisation temperature so as to reduce the risk of thermal shock on the tissues,
6. high-molecular-weight polymer to improve the fatigue strength of the implant.

**STANDARD VISCOSITY CEMENTS: G1™ and G1A™**

**PLAIN BONE CEMENTS**
- G1™
- PALACOS® R
- SIMPLEX® P

**BONE CEMENTS WITH ANTIBIOTIC**
- G1A™
- PALACOS® R+G
- CEMEX® GENTA HV

**MECHANICAL STRENGTH AND HARDENING TEMPERATURE ACCORDING TO ISO 5833**

**BENDING STRENGTH**
- G1™
- PALACOS® R
- SIMPLEX® P
- 50 MPa = ISO 5833 minimum requirement

**BENDING MODULUS**
- G1™
- PALACOS® R
- SIMPLEX® P
- 1800 MPa = ISO 5833 minimum requirement

**COMPRESSIVE STRENGTH**
- G1™
- PALACOS® R
- SIMPLEX® P
- 70 MPa = ISO 5833 minimum requirement

**HARDENING TEMPERATURE**
- G1™
- 90°C = ISO 5833 maximum requirement

2. Data on file at G-21 S.r.l.
Acrylic-based radiopaque bone cement with a consistency and working time particularly suitable for cementation of hip prostheses and where you need to work on medium/small joints.

Ideal for use with mixing and injection devices. The version with antibiotic is indicated in revision operations and in cases where there is a risk of infections caused by organisms sensitive to gentamicin. It has been demonstrated that local application of antibiotics by means of bone cement reduces the risk of septic detachment of the prosthesis, assuring high release of active ingredient in the implant site while maintaining the concentration on systemic level low.

**CHARACTERISTICS**

1. reduced mixing time (under a minute to obtain a homogeneous product),
2. working time suited to the type of application (6-8 minutes),
3. polymerisation is completed after 13 minutes so as to reduce the risk of micro movements of the prosthesis once applied,
4. excellent mechanical properties,
5. low polymerisation temperature so as to reduce the risk of thermal shock on the tissues,
6. high-molecular-weight polymer to improve the fatigue strength of the implant.

**LOW VISCOSITY CEMENTS: G3™ and G3A™**

**MECHANICAL STRENGTH AND HARDENING TEMPERATURE ACCORDING TO ISO 5833**

### PLAIN BONE CEMENTS

- **G3TM**
- **PALACOS LV**
- **CEMEX RX**

#### BENDING STRENGTH

- G3TM: 50 MPa (ISO 5833 minimum requirement)
- PALACOS LV: 50 MPa (ISO 5833 minimum requirement)
- CEMEX RX: 50 MPa (ISO 5833 minimum requirement)

#### BENDING MODULUS

- G3TM: 1800 MPa (ISO 5833 minimum requirement)
- PALACOS LV: 1800 MPa (ISO 5833 minimum requirement)
- CEMEX RX: 1800 MPa (ISO 5833 minimum requirement)

#### COMPRESSIVE STRENGTH

- G3TM: 70 MPa (ISO 5833 minimum requirement)
- PALACOS LV: 70 MPa (ISO 5833 minimum requirement)
- CEMEX RX: 70 MPa (ISO 5833 minimum requirement)

#### HARDENING TEMPERATURE

- G3TM: 90°C (ISO 5833 maximum requirement)
- PALACOS LV: 90°C (ISO 5833 maximum requirement)
- CEMEX RX: 90°C (ISO 5833 maximum requirement)

### BONE CEMENTS WITH ANTIBiotic

- **G3ATM**
- **PALACOS LV+G**
- **CEMEX GENTA LV**

#### BENDING STRENGTH

- G3ATM: 50 MPa (ISO 5833 minimum requirement)
- PALACOS LV+G: 50 MPa (ISO 5833 minimum requirement)
- CEMEX GENTA LV: 50 MPa (ISO 5833 minimum requirement)

#### BENDING MODULUS

- G3ATM: 1800 MPa (ISO 5833 minimum requirement)
- PALACOS LV+G: 1800 MPa (ISO 5833 minimum requirement)
- CEMEX GENTA LV: 1800 MPa (ISO 5833 minimum requirement)

#### COMPRESSIVE STRENGTH

- G3ATM: 70 MPa (ISO 5833 minimum requirement)
- PALACOS LV+G: 70 MPa (ISO 5833 minimum requirement)
- CEMEX GENTA LV: 70 MPa (ISO 5833 minimum requirement)

#### HARDENING TEMPERATURE

- G3ATM: 90°C (ISO 5833 maximum requirement)
- PALACOS LV+G: 90°C (ISO 5833 maximum requirement)
- CEMEX GENTA LV: 90°C (ISO 5833 maximum requirement)

2. Data on file at G-21 S.r.l.
RELEASE OF ANTIBIOTIC AND FATIGUE STRENGTH

STANDARD VISCOSITY BONE CEMENTS

G3ATM(1) PALACOS®LV+G(2) CEMEX®GENTA LV(2)

LOW VISCOSITY BONE CEMENTS

G3ATM(1) PALACOS®LV+G(2) CEMEX®GENTA LV(2)

1. Data on file at G-21 S.r.l.

G1ATM µg/g

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<td>GENTA LV</td>
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G3ATM µg/g

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<td>GENTA LV</td>
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1. Test carried out at the Laboratory of Biological Structure Mechanics - Structural Engineering Department of the Polytechnic Institute of Milan. Data on file at G-21 S.r.l.

Comparison between G-21’s antibiotic-loaded bone cements aged samples(1) (according to ISO 16402:2008(2)) and results published by Linden(3)

At a stress level of 20 MPa, G-21’s hand-mixed samples showed better performance in comparison to well-established bone cements made by Zimmer and DePuy(3).

FATIGUE STRENGTH - MEAN FAILURE LIFE AT 20 MPa

G-21’s BONE CEMENTS

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<tr>
<td>G-21 A</td>
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<td>ZIMMER LVC</td>
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At a stress level of 20 MPa, G-21’s hand-mixed samples showed better performance in comparison to well-established bone cements made by Zimmer and DePuy(3).

ORDERING INFORMATION

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<thead>
<tr>
<th>PRODUCT</th>
<th>COMPOSITION</th>
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<tr>
<td>G1 20™</td>
<td>Standard viscosity radiopaque bone cement</td>
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<td>Standard viscosity radiopaque bone cement</td>
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<td>G1A 20™</td>
<td>Standard viscosity radiopaque bone cement with antibiotic</td>
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<td>Standard viscosity radiopaque bone cement with antibiotic</td>
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HiVac™ Bowl
Bone cement closed mixing system

Mixer design has been found to significantly influence the quality of cement. The original unique geared rotational axis mixing mechanism of HiVac™ Bowl ensures a reproducibly high quality mix of bone cement, significantly better than that created by hand mixing or a fixed axis bowl.

HiVac™ Bowl allows cement to be mixed at optimal levels of porosity to maximise fatigue resistance of the cement. To further enhance fatigue life, cement needs to be mixed under optimal vacuum levels. If the vacuum level is too low then the cement will contain high levels of porosity, but if too high, excessive thermal shrinkage can create cracking in the cement mantle. The HiVac™ range operates at 550 mmHg, which has been shown to give improved mechanical properties.

Charcoal / microbiological filter reduces exposure to methylmethacrylate (MMA) fumes in theatre to levels significantly below those set out in the Health and Safety Executive guidelines.

The mixing bowl can be operated with ease, on or off a flat surface. High clarity material allows the mixing process to be viewed from any position. HiVac™ Bowl is latex free and includes a spatula and a disposable curette for scraping, shaping and cutting bone cement.

Disp Mixing Bowl-O™
Open mixing system for bone cement preparation

Latex free, disposable plastic bowl supplied sterile packed with a spatula for mixing and a surgical drape.

HiVac™7
Bone cement mixing and delivery system

This evolution of piston-style mixing devices is suitable for mixing quantities of cement up to 120 g. HiVac™7 has a narrow mixing tube which, in combination with a new gun, provides the surgeon with precise control over cement extrusion and the potential to generate increased delivery pressures.

HiVac™7 features a clear tube allowing the clinician to have an unclouded view of the cement during mixing. This offers peace of mind to the user as mix quality can be visually assessed prior to delivery.

To further enhance fatigue life, cement needs to be mixed under optimal vacuum levels. If the vacuum level is too low then the cement will contain high levels of porosity, but if too high, excessive thermal shrinkage can create cracking in the cement mantle. The HiVac™7 range operates at 550 mmHg, which has been shown to give improved mechanical properties.

It remains a closed system during the mixing and delivery process. In addition, charcoal / microbiological filter reduces exposure to methylmethacrylate (MMA) fumes in theatre to levels significantly below those set out in the Health and Safety Executive guidelines.

The mixing rod has a blue section allowing the user to gain accurate alignment, ensuring that when required, the rod is easily and reliably snapped. HiVac™7 has an elegant ergonomic design, so that the mixer can comfortably be used on a trolley or held in the hand.

Vacuum Footpump 550™
Vacuum pump with foot switch